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EXAMINER

BROWN JR, NATHAN H

ART UNIT	PAPER NUMBER
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2129

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/674,270	Applicant(s) DE VOIR ET AL.	
	Examiner NATHAN H. BROWN JR	Art Unit 2129	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE (3) MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Examiner's Detailed Office Action

1. This Office Action is responsive to the communication for application 10/674,270, filed August 27, 2008.
2. Claims 1-6 and 8-17 are pending. Claims 1-6 and 8-17 are previously presented.
3. After the previous office action, claims 1-6 and 8-17 stood rejected.

Objections to the Claims

4. Claim 1 is objected to because of the following informalities: "a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation" should be --a transformation unit which is designed to carry out transformation of the physiological signal in such a way that it outputs a number of values representing the physiological signal and based on the transformation--.
Appropriate correction is required.

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Claim Rejections - 35 USC § 112, 1st

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 1 recites an "apparatus for the classification of physiological events" having "a transformation unit which is designed to carry out transformation of the physiological signal *in such a way that it outputs* a number of values representing the physiological signal and based on the transformation" [emphasis added]; however no processor, memory, or machine readable medium is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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transformation unit designed to carry out transformation of a physiological signal.

7. Claims 1-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Independent claim 1 recites an "apparatus for the classification of physiological events" having "a transformation unit which is designed to carry out transformation of the physiological signal *in such a way that it outputs* a number of values representing the physiological signal and based on the transformation" [emphasis added]; however no processor, memory, or machine readable medium is described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the transformation unit designed to carry out transformation of a physiological signal.

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-6 and 8-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter: non-functional descriptive material or software per se. Independent claim 1 recites an "apparatus for the classification of physiological events" having "a transformation unit which is designed to carry out transformation of the physiological signal *in such a way that it outputs* a number of values representing the physiological signal and based on the transformation" [emphasis added]; however the transformation unit is not defined in terms of a functional arrangement of a processor, memory, or machine readable medium. Therefore, the "transformation unit" (unlike the "signal preparation unit" which *is* defined in terms of function hardware, i.e., an: anti-aliasing filter, broadband analog-digital converter or A/D-converter) is considered to be a non-functional description or software per se. Thus, independent claim 1 is considered to be non-statutory under 35 U.S.C. 101. Claims 2-6 and 8-17 provide further technical limitation to claim 1, but do not cure the deficiency of claim

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1. Therefore, claims 1-6 and 8-17 are considered to be non-statutory under 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this

Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Esteller et al.** (*Esteller*) (USPN 6,594,524) in view of **Gillberg** (USPN 6,393,316).

Regarding claim 1. (Previously presented) *Esteller* teaches an apparatus for the classification of physiological events (see Abstract, Examiner interprets "forecasting" to be a classification task where the input is a description of some

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earlier event and the output is the identification of some event that follows (or results from) the earlier event.), comprising:

a signal input for the input of a physiological signal representing or constituting a physiological event (see col. 9, lines 34-36);

a classification unit (see Fig. 3, item 200 "Intelligent Data Processing Unit") for classifying the physiological signal on the basis of its signal shape (see col. 18, lines 44-50), the classification unit comprising:

a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation (see Fig. 4, preprocessing 210 and feature extraction; col. 9, lines 20-25; col. 20, lines 26-36); and

a probabilistic neural network which is connected to the transformation unit to receive the values (see Fig. 32, col. 36, lines 43-50) and which contains a number of event classes which represent physiological events (see Fig. 32, col. 36, lines 30-33) and which in turn are each represented by a set of comparative values, which probabilistic neural network is adapted on the basis of the comparison of the values with the comparative values to effect

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an association of the physiological signal represented by the values with one of the event classes (see col. 36, lines 55-56 and col. 37, lines 27-36, *Examiner interprets "weights used at the hidden layer of the PNN" to be comparative values, which the probabilistic neural network is adapted on.*).

Esteller does not teach an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit.

However, *Gillberg* does teach an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit (see Figs. 2 and 6 and col. 16, lines 15-24, "The 64 sample segment of data (254 milliseconds) was extracted from a continuous multi-channel recording using the technique of centering a morphology window around the bipolar sensed ventricular depolarization...", *Examiner interprets the "Microprocessor 524" to be an adjusting unit connected upstream of the transformation unit "A/D 530 and RAM 526" (see Fig. 2).*).

It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine *Esteller* with *Gillberg* to monitor heart rhythms.

Regarding claim 2. *Esteller* teaches the apparatus of claim 1, wherein: the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets (see col. 28, lines 21-44).

Regarding claim 3. *Esteller* teaches the apparatus of claim 2, wherein: the comparative values of the probabilistic neural network are based on a transformation procedure in which the same wavelets and the same transformation rule as in the transformation unit are used (see Fig. 32, col. 37, lines 10-17; inputs of the neural network come from the outputs of transformation unit, therefore said comparative values are based on the transformation procedure).

Claim Rejections - 35 USC § 103

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12. Claims 4-6, 8, 9, and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Esteller** in view of **Gillberg** and further in view of **Echauz et al.** (*Echauz*) (USPN 6,678,548).

Regarding claims 4, 11, and 12. *Esteller* teaches the apparatus of claim 3, wherein the probabilistic neural network further comprises: at least one ascertaining unit for determining association probabilities of the physiological signal with the event classes on the basis of the comparison of the values with the comparative values of the respective event class and for outputting the ascertained association probabilities (see Fig. 32, col. 37, lines 11-20). *Esteller* does not expressly teach selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability (it is disclosed in Fig. 32 as competitive layer, but without a detailed explanation). However, *Echauz* teaches selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the

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event class having the highest association probability (see col. 26, lines 36-39 mention competitive layer as a maximum selector; see also col. 18, lines 53-66). It would have been obvious to a person of ordinary skill in the art at the time of the invention to include the details on implementation of a probabilistic neural network from *Echaz* and combine it with the probabilistic neural network of *Esteller* and *Gillberg* in order to find the details of how the probability of having a seizure is estimated.

Regarding claim 5. *Esteller* teaches the apparatus of claim 4, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see col. 13, lines 39-44).

Regarding claim 6. *Esteller* teaches the apparatus of. claim 5, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (see Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and , upon

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extraction of the highest association probability uses the average values instead of the individual values (see Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T1 and T2 form probabilities PI and P2 correspondingly).

Regarding claim 8. *Esteller* teaches the apparatus of claim 6. *Esteller* does not teach the apparatus of claim 6, wherein: in those event classes which include two or more sets of comparative values representing the same event class, the sets of comparative values correspond to different offsets in the centering of the centered physiological signal. *Gillberg* does teach that, in those event classes which include two or more sets of comparative values representing the same event class (see col. 15, lines 28-57, *Examiner interprets "unknown" EGM waveforms' to be an event class which includes two or more sets of comparative values (i.e., "EGM waveforms from the ongoing rhythm are obtained at 306") representing the same event class.*), the sets of comparative values correspond to different offsets in the centering of the centered physiological signal (see Fig. 6 and col. 3, line 15 to col. 16, line 14, *Examiner interprets the wavelets derived from the DWT that describe "the signal in terms of a basis that represents the features of the*

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signal at different time-scales (i.e. resolutions)" to be sets of comparative values correspond to different offsets in the centering of the centered physiological signal.)). It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine Esteller with Gillberg to monitor heart rhythms.

Regarding claim 9. *Esteller* teaches an implantable medical device characterized in that it is provided with an apparatus for the classification of physiological events as set forth in claim 8 (see Abstract).

Regarding claim 10. *Esteller* teaches the implantable medical device of claim 9 (see Abstract). *Esteller* does not teach that the implantable medical device is in the form of a cardiac pacemaker or defibrillator. *Gillberg* does teach that the implantable medical device is in the form of a cardiac pacemaker or defibrillator (see col. 1, lines 10-13). It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine *Esteller* with *Gillberg* to monitor heart rhythms.

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Regarding claim 13. *Esteller* teaches the apparatus of claim 1, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see col. 13, lines 39-44).

Regarding claim 14. *Esteller* teaches the apparatus of claim 11, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see col. 13, lines 32-36, *Examiner interprets "electrical, magnetic, chemical, sensorial or cognitive stimulation variables" to be comparative values representing the same event class are present for at least one event class.*).

Regarding claim 15. *Esteller* teaches the apparatus of claim 12, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see above).

Regarding claim 16. *Esteller* teaches the apparatus of claim 14, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (see Fig. 32, col. 37, lines 21-26,

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Examiner interprets the entries of Matrix T to determine a plurality of association probabilities for each event class.), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities (see Fig. 32, Examiner interprets the output units P_1 and P_2 to form the average of T_{1j} and T_{2j} , respectively, where each T_{ij} is "the probability that the input signals belong to the pre-seizure/seizure class".) and upon extraction of the highest association probability uses the average values instead of the individual values (see Fig. 32, Examiner interprets the units of the "Competitive Layer" to extract the highest association probability by picking one of P_1 or P_2 which use the average of T_{1j} and T_{2j} , respectively.).

Regarding claim 17. *Esteller teaches the apparatus of claim 15, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (see Fig. 32, col. 37, lines 22-26, Examiner interprets the entries of Matrix T to comprise two or more sets of comparative values representing the same event*

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class (e.g., T11 and T21 emanate from the same hidden unit, which represents a class of pre-seizure data).), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average, values of the corresponding association probabilities and upon extraction of the highest association probability uses the average values instead of the individual values (see Fig. 32, Examiner interprets the units of the "Competitive Layer" to extract the highest association probability by picking one of P_1 or P_2 which use the average of T_{1j} and T_{2j} , respectively.).

New grounds of rejection have been added.

Response to Arguments

13. Applicant's arguments filed August 27, 2008 have been fully considered.

Rejection of Claims 1-6 and 8-17 Under 35 U.S.C. §112, first paragraph

Applicant(s) argue(s):

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The idea that the physiological signal of the claimed invention of claim 1 is automatically time-centered in a time window is well supported by the specification. The following refers to the substitute specification of the present application:

The entire specification is written in the context of implantable medical devices such as cardiac pacemakers and defibrillators. All internal functions of such devices are inherently automatic.

Examiner responds:

Examiner finds applicants' arguments persuasive; however, the arguments are moot, based on new grounds of rejection. Applicants' arguments in this area also raise new grounds of rejection under U.S.C 112 and U.S.C 101.

Rejection of Claims 1-3 Under 35 U.S.C. §103(a)

Applicant(s) argue(s):

In the current Office action, claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller (US 6,594,524), hereinafter Esteller, in view of Voelz (US 4,779,100), hereinafter Voelz. The Examiner finds no recitation of "automatically time-centering a physiological signal" in Applicants' specification and thus considers the Applicants' argument moot.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Esteller does not teach or suggest an adjusting unit for automatically time-centering a physiological signal with respect to the time dimension in a time window of predetermined window width in the time dimension as does the claimed invention of claim 1. Furthermore, Voelz does

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not teach or suggest an adjusting unit for automatically time-centering a physiological signal with respect to the time dimension in a time window of predetermined window width in the time dimension as does the claimed invention of claim 1.

Examiner responds:

Applicants' arguments are moot, based on new grounds of rejection.

Correspondence Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan H. Brown, Jr. whose telephone number is 571-272- 8632. The examiner can normally be reached on M-F 0830-1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Vincent can be reached on 571-272-3080. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

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see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Nathan H. Brown, Jr./
Examiner, Art Unit 2121
November 4, 2008

/David R Vincent/

Supervisory Patent Examiner, Art Unit 2129